

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

HOLLISED.063A

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

on _____

Signature _____

Typed or printed name _____

Application Number

09/675,323

Filed

September 28, 2000

First Named Inventor

Henry Lardy

Art Unit

1623

Examiner

Elli Peselev

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☒ attorney or agent of record.
Registration number 36,616

☐ attorney or agent acting under 37 CFR 1.34.

Registration number if acting under 37 CFR 1.34 _____



Signature

Daryl D. Muenchau

Typed or printed name

858-587-9333

Telephone number

July 19, 2006

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below.

☐ Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Henry Lardy, et al.
Application No. : 09/675,323
Filed : September 28, 2000
Title : Therapeutic Treatment of Androgen Driven Conditions
5 Examiner : Elli Peselev
TC/A.U. : 1623

Docket No. : HOLISED.063A
Customer No. : 26551
10 Confirmation No. : 2363

15 **PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
20 Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of the final rejection in the above-identified
25 application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

Applicants request this review for the reasons stated, which begin on page

2.

The undersigned is the attorney of record (reg. No. 36,616).

INTRODUCTION

Applicants are filing this review request in response to the final office action the Office mailed on June 23, 2006. A notice of appeal and provision for payment of the fee accompanies this request. The claims in this application recite methods to treat clinical conditions associated with androgen receptor activity. Applicants request reconsideration of the rejection for the reasons discussed below.

DOUBLE PATENTING

Office finally rejected claims 56-59, 61, 63-65 and 67-69 of the present patent application as allegedly obvious over claim 15 of copending patent application No. 10/319,356. As discussed below, the rejection is improper and should be withdrawn.

Obviousness-type double patenting was developed to cover the situation where patents or applications are not citable as a reference against each other and therefore can not be examined for compliance with the rule that only one patent is available per invention. Double patenting is thus applied when neither patent is prior art against the other, usually because they have a common priority date. *Eli Lilly and Co. v. Barr Laboratories Inc. et al.*, 251 F.3d 955, 58 U.S.P.Q. 2D 1865 (Fed. Cir. 2001). Copending application No. 10/319,356 does not share a common priority date with this application and obviousness-type double patenting does not apply to these two applications. Applicants request reconsideration and withdrawal of the rejection over copending application No. 10/319,356.

On two occasions, Applicants stated that claim 15 of copending patent application No. 10/319,356 had been canceled, with the pending claims in that application directed to treating inflammation conditions. Applicants reiterate this assertion. The attached sheets are pages 1 and 3 of the February 24, 2006 petition and amendment that included cancellation of claim 15 in the 10/319,356 application. The attached sheets are a copy of the amendment in the 10/319,356

application image file wrapper. The amendment canceling claim 15 is at line 14 of page 3 in that amendment. Since claim 15 in the 10/319,356 application is canceled, the rejection should be withdrawn.

Respectfully submitted,

Date: July 19, 2006



Daryl D. Muenchau, Reg. No. 36,616
Hollis-Eden Pharmaceuticals, Inc.
4435 Eastgate Mall, Suite 400
San Diego, CA 92121
Phone: 858-320-2569

Attachment:

Copy of pages 1 and 3 from the February 24, 2006 petition and amendment in the file for U.S. application No. 10/319,356



TFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

COPY

Applicant : Clarence N. Ahlem, et al.
App. No. : 10/319,356
Filed : December 13, 2002
Title : Pharmaceutical Compositions and Treatment Methods
Examiner : Alton N. Pryor
Group Art Unit : 1616
Confirmation No. : 9113
Customer No. : 26551

PETITION TO REVIVE AN UNINTENTIONALLY ABANDONED
APPLICATION UNDER 37 CFR 1.137(B)
AND AMENDMENT AND RESPONSE TO OFFICE ACTION

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants hereby petition for revival of this application.

This petition to revive an unintentionally abandoned application under 37 CFR § 1.137(b) is submitted in response to the notice of abandonment the office sent on February 23, 2006 and a reply to the office action the Office mailed on June 2, 2004 is included. Provision for payment of the petition fee under 37 CFR 1.17(m) accompanies this petition and a statement that the entire delay was unintentional is also included.

Amendments to the specification begin on page 2.

Amendments to the claims begin on page 3.

Remarks for the petition and office action begin on page 6.

AMENDMENTS TO THE CLAIMS**COPY**

Please amend the claims as follows.

- 5 1 (currently amended): A method to treat an inflammation condition or
prevent ~~a pathological condition selected from the group consisting of a pathogen
infection, an autoimmune disease, an allergy or inflammation condition, a cancer
or a precancer, a neurological disorder, a wound, a burn, a bone fracture,
osteoporosis, acute myelitis, sarcoidosis or an immune suppression condition or~~
10 unwanted immune response associated with a chemotherapy, a radiation therapy
or aging in a subject in need thereof, comprising administering to the subject an
effective amount of 16 α -bromo-3 β -hydroxy-5 α -androstan-17-one hemihydrate.

Claims 2-18 (cancelled)

15

- 19 (currently amended): The method of claim 18, ~~wherein the allergy or~~
claim 1 wherein the inflammation condition is allergic bronchopulmonary
aspergillosis, atopic asthma, ~~allergic respiratory disease, allergic rhinitis, atopic~~
asthma, sarcoidosis, rheumatoid arthritis, osteoarthritis, atopic dermatitis, lung
20 fibrosis, subepithelial fibrosis in airway hyperresponsiveness, chronic sinusitis,
~~perennial allergic rhinitis, Crohn's disease, ulcerative colitis, inflammatory bowel~~
disease, chronic diarrhea or fibrosing alveolitis.

Claims 20-23 (cancelled)

25

- 24 (currently amended): The method of claim 19 ~~claim 1, 2, 13, 16, 18 or~~
20 wherein the subject is a human.

- 25 (original): The method of claim 1 wherein the 16 α -bromo-3 β -hydroxy-
30 5 α -androstan-17-one hemihydrate is administered to the subject in a buccal or
sublingual formulation.